

REMARKS

The first rejection, of all of pending claims 40-48 is a lack of enablement rejection.

According to the Examiner, undue experimentation would be required to make and use an HCV assay wherein the polypeptide merely consists of a portion of the NS3 region. According to the Examiner, no working examples using a portion of NS3 are disclosed.

First, “antigen NS3” is not the complete NS3 protein. See, e.g., Wiesch, et al., Archives of Virology, 148:1247-1267 (2003), copy attached, page 1249 in particular, showing NS3 spanning amino acids 1026-1657.

With respect to the alleged undue experimentation where cysteine residues are modified, example 5 discusses the use of portions of NS3, i.e., the HCV-NS3 helicase region, under conditions which included 20 mmol/l DTT. This is a strong reducing agent, which is known to modify cysteine residues. The use of the reducing conditions actually improved the assay. See the end of page 20, and the Table at page 21, discussing a comparison of the use of a portion of NS3 under reducing and non-reducing conditions. Hence, if this example is considered carefully, the evidence will be seen to support the claims.

The Examiner then rejects claims 43, 46, and 47, alleging that they are drawn to specific, unsupported peptides.

The amino acid sequences discussed in the claims are described. For example, the specification discusses “NS3 polypeptide” as consisting of amino acids 21-282 of SEQ ID No: 9. It is the same as amino acids 1207-1488 from the NS3 region of the hepatitis C virus region, as has been developed at great length during the prosecution of this application, and prior applications in the family. With respect to the additional 20 amino acids, all one has to do to find an example is to look to SEQ ID NO: 9, for example. If the NS3 polypeptide is amino acids 21-282, then clearly a peptide with 1-20 amino acids appended thereto is taught. Further, the term “90% homology” has been developed

during prosecution, and if a reference molecule is known, one can certainly speak of 90% homology, and expect the skilled artisan to understand this.

With respect to the Written Description requirement, as was pointed out, supra, the specification provides evidence of what is claimed. The University of Rochester case is not relevant, since in that case, there was a claim to a product which resulted from a disclosed screening method, but no such products were disclosed. Such is not the case here, as has been established.

In claim 43, the point is that the 20 amino acids are concatenated to either terminus, of the amino acid sequence consisting of amino acids 21-282, as described, or to either terminus of a peptide 90% homologous to this specific amino acid sequence. It is believed claim 43 is absolutely clear. If the Examiner disagrees, he should suggest language he finds appropriate.

All issues are believed to have been addressed, and all rejections overcome. Allowance of the application is believed proper and is urged.

Respectfully submitted,

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Enclosure: Reference